

REMARKS/ARGUMENTS

Claims 1-4, 6-9, and 11-19 are pending in this application. Claims 15-18 have been withdrawn, without prejudice to the subject matter contained therein, from further consideration on the merits as being directed toward the non-elected invention. Claims 5 and 10 are canceled via the instant amendment. Claim 19 replaces claim 10, which was indicated as being free of the prior art, and incorporates all intervening subject matter of original claim 10, as well as the instant amendments.

In response to the Office Action of February 26, 2003, Applicant requests re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Objections to the Claims:

Claims 2-14 are objected to as being ungrammatical. Claim 2 and claims dependent therefrom recite "the group consisting of ionizable or permanently charged repeating units".

The Examiner has indicated that a group cannot consist of one species or another species, because a species in itself is not a group. It is suggested that the word "and" should be substituted for the word "or" in this context. Similarly, claim 4 is deemed to require selection from "the group consisting of a

change in pH or conduction of a chemical reaction". It is suggested that either the word "and" should be substituted for the word "or", or the phrase "selected from the group consisting of" should be deleted.

The Examiner further notes that the Markush group in claim 1 could be set forth more clearly by rewriting it in outline form.

For example "... selected from the group consisting of

a. diblock copolymers including ionizable and permanently charged units;

b. multiblock copolymers including ionizable units, permanently charged units, or mixtures of ionizable and permanently charged units;

and

c. random copolymers with grafted hydrophilic and essentially non-ionic oligomers or polymers, said random copolymers including ionizable units, permanently charged units, or mixtures of ionizable and permanently charged units;" etc.

At a minimum, it is suggested that commas should be inserted between the words "units" and "or" in each instance of the phrase "permanently charged units or".

The claims have now been corrected in accordance with the Examiner's suggestions.

Rejections under 35 USC 112

Claims 1-14 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 are deemed to be indefinite because it is unclear what is intended by "essentially non-ionic". The specification is deemed to fail to define "essentially" in this context, so it is unclear what are the metes and bounds of the claims. It is unclear what amount of ionic character is acceptable.

Claims 1-14 are also deemed to be indefinite because it is unclear what are the metes and bounds of "permanently charged units". The Examiner indicates that he is unaware of water soluble molecules comprising electrostatic charges that cannot be neutralized by at least one of adjustment of pH, addition of a salt, or chemical modification (as recited in claim 4). The Examiner therefore concludes that it would seem that any "permanently charged" molecule could be changed to a transiently

charged, or uncharged, molecule by an appropriate chemical reaction.

Similarly, claims 2-14 are indicated as being indefinite because it is unclear what is intended by "essentially uncharged" or "essentially hydrophobic". The specification is indicated as failing to define "essentially" in these contexts, so it is unclear what are the metes and bounds of the claims. It is further deemed unclear as to what amount of charge or hydrophilic character is acceptable.

Claims 3 and 4 are deemed to be indefinite because it is unclear what is intended by "external stimulus". Specifically, it is deemed unclear to what the stimulus must be external, so the metes and bounds of the claim are unclear. Deletion from claim 3 of "via an external stimulus" is suggested. Substitution of "transformation to a charged state is caused by" for "said external stimulus is selected from the group consisting of" is further suggested.

Similarly, claim 5 is indefinite because it is unclear what is intended by "external conditions". Specifically, it is unclear to what the conditions must be external, so the metes and bounds of the claim are unclear.

Claims 7, 8, 11, and 13 are deemed to be indefinite because it is unclear what are the metes and bounds of the term "derivatives".

Claim 8 is deemed indefinite because it recites "said alkyl or aryl derivatives" without proper antecedent basis.

The claims have now been amended in accordance with the Examiner's suggestions. No new matter is added.

Rejections under 35 USC 102(b)

Claims 1-4 and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al (US Patent 5,510,103, issued 4/23/96). Yokoyama is deemed to teach micelles composed of diblock copolymers comprising hydrophilic blocks and blocks comprising ionizable residues and hydrophobic repeating units. The Examiner emphasizes that in one embodiment of the invention the hydrophilic block is non-ionizable polyoxyethylene, and the ionic block ionizable moiety is an acetic or propionic acid group (see claim 1, especially line 27 wherein R3 may be propionic acid). The Examiner further indicates that the propionic acid comprises a hydrophobic segment (ethylene group) that serves as a non-ionic hydrophobic repeating unit and that the propionic acid group can be converted between charged and

uncharged states by altering the pH of the medium, or by chemical modification, e.g. covalent addition of an uncharged group (see claim 1, lines 30-35). Claim 14 is included in this rejection because it is a product by process in which the claimed product is deemed to be disclosed in the cited art, rendering the process by which it was made irrelevant, according to the Examiner.

For the above reasons, the Examiner concludes that Yokoyama is deemed to be anticipatory of the claims.

Yokoyama teaches block copolymer micelles composed of a poly(ethylene oxide) segment linked to another homopolymer segment. The latter segment features only one type of repeating unit. It is respectfully submitted that Yokoyama fails to anticipate the instantly claimed invention. For example, in the example selected by the Examiner(propionic acid group), the propionic acid bears both a hydrophobic segment and an ionizable group. The instantly claimed invention distinguishes over Yokoyama in that the ionizable and hydrophobic units are distinct. As amended, the claims specify that the hydrophobic units are non-ionic. Therefore the ratio of ionic/non-ionic units can be varied. This is not possible in the Yokoyama patent.

The use of non-ionic hydrophobic units in the instant invention make possible the micellization of block copolymers of methacrylic acid and poly(ethylene glycol) at acidic pH (example 2) and the micellization of block copolymer of poly(ethylene glycol) and amine-based methacrylates (example 1).

Such combinations are neither taught nor suggested by Yokoyama et al.

For the above reasons it is respectfully submitted that the reference to Yokoyama et al fails to anticipate the invention as instantly claimed and allowance of said instant claims is respectfully solicited.

Rejections under 35 USC 102(e)

Claims 1-9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Allwohn et al (US Patent 6,372,203, issued 4/16/02).

Allwohn is deemed to teach micellar compositions comprising diblock copolymers of hydrophilic saccharide polymers and polymers of charged monomers comprising hydrophobic repeating units. The Examiner directs Applicant to column 4, lines 56-59; column 5, lines 24'-67; column 6, line 43 to column 7, line 8; and column 10, lines 39-46. In one embodiment, it is indicated

that the charge can be viewed as permanent, i.e. a quaternary amine (see column 5, lines 34-37. In another embodiment, it is indicated that the charge is subject to pH (secondary and tertiary amines, see column 5, lines 34-37). It is further indicated that the hydrophobic repeating units required by the claims can be considered to be the vinyl groups, acrylate derivatives, C₁ to C₁₂ alkyl groups, or aryl groups (see column 5, lines 37-55). In a further embodiment, the Examiner points out that the copolymer comprising the charged and hydrophobic entities is a polymer of vinyl esters (see column 6, line 64 to column 7, line 8).

For the above reasons the Examiner concludes that Allwohn is anticipatory of the claims.

The reference to Allwohn et al fails to disclose a supramolecular self-assembly or micelle as instantly claimed. An essential feature of the instant invention is that the polyelectrolyte self assembles to form a supramolecular structure with a hydrophobic core. This is neither disclosed nor taught by Allwohn et al, and thus it is respectfully requested that this ground of rejection be withdrawn.

Claims 1-5, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Kabanov et al (US Patent 6,440,743,

issued 8/27/02).

Kabanov is deemed to teach micellar compositions comprising diblock, multiblock, and random graft copolymers comprising a hydrophilic, nonionic polymer and a polycationic polymer with hydrophobic repeating units. The Examiner references the entire document, especially the abstract, column 3, line 30 to column 6, line 64; and column 10, lines 4-49. In one embodiment, it is indicated that the charge can be viewed as permanent, i.e. a quaternary amine (see column 10, lines 11 and 12. In another embodiment, it is indicated that the charge is subject to pH (secondary and tertiary amines, see column 10, lines 9 and 10). The Examiner indicates that the hydrophobic repeating units required by the claims can be considered to be the ethylene, propylene, butylene, pentylene, or hexylene (see column 10, lines 6-9). The Examiner further indicates that the hydrophilic block may comprise acrylamide or acrylamide derivatives.

Kabanov teaches a composition comprising a noncovalent complex of polynucleotide and polymer. What defines this patent is the complex formation between a polycation and a polynucleotide, which is negatively charged. Kabanov does not teach or suggest polyelectrolyte self-assemblies that can be obtained without any complexation to oppositely-charged

molecules. The instant claims are not restricted to polycations, but more importantly, the polyelectrolyte chains can form supramolecular assemblies in the absence of any polynucleotides. This makes the micelles more resistant toward dissociation in aqueous media.

Furthermore, the instant claims patentably distinguish over Kabanov et al since the limitation of "non-ionic hydrophobic units" is neither taught nor suggested by Kabanov et al.

Thus it is respectfully submitted that this ground of rejection be withdrawn and the claims passed to issue.

SUMMARY

In light of the foregoing remarks and amendment to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



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